

(e) a representative of the Food and Drug Administration, Department of Health, Education, and Welfare, inspects the plant and determines that adequate control systems have been installed as listed herein, and as considered necessary in the manufacturing of ophthalmic products.

**6321. Vitamin B<sub>12</sub> injection.** (F.D.C. No. 44485. S. No. 27-407 R.)

**QUANTITY:** 776 individually ctnd. vials at Minneapolis, Minn., in possession of Ulmer Pharmacal Co.

**SHIPPED:** 1-13-60, from Decatur, Ill.

**LABEL IN PART:** (Ctn. and vial) "L.F.B. 12-100 10 cc. For Intramuscular Injection Cat. No. 2185 Each cc. contains: Vitamin B<sub>12</sub> Activity (From Liver Injection U.S.P. Beef) Equivalent to: Cyanocobalamin 10 mcg. \* \* \* Fortified with: \* \* \* Vit. B<sub>12</sub> Cryst. 100 mcg. \* \* \* The Ulmer Pharmacal Company, Minneapolis 3, Minnesota."

**RESULTS OF INVESTIGATION:** Examination showed that the article contained approximately 79 percent of the declared amount of vitamin B<sub>12</sub>.

**LIBELED:** 6-8-60, Dist. Minn.

**CHARGE:** 501(c)—while held for sale, the strength of the article fell below that which it purported to possess; and 502(a)—the unqualified label statement "The Ulmer Pharmacal Company, Minneapolis 3, Minnesota" suggested and implied that the Ulmer Pharmacal Co., was the manufacturer of the article which statement was misleading since the Ulmer Pharmacal Co., was not the manufacturer of the article; and the label statement "Each cc, contains \* \* \* Vitamin B<sub>12</sub> activity \* \* \* equivalent to \* \* \* Cyanocobalamin 10 mcg." was false and misleading as applied to an article that contained less than the declared amount of vitamin B<sub>12</sub>.

**DISPOSITION:** 7-26-60. Default—destruction.

**6322. Chorionic gonadotropin injection.** (F.D.C. No. 44504. S. No. 8-858 R.)

**QUANTITY:** 14 pkgs., each containing 1 10-cc. vial of chorionic gonadotropin and 1 10-cc. vial of a diluent at New Hartford, N.Y.

**SHIPPED:** 4-10-58, from Chicago, Ill.

**RESULTS OF INVESTIGATION:** Analysis of the article showed that it contained less than 2,500 international units of chorionic gonadotropin potency per vial.

**LIBELED:** 6-21-60, N. Dist. N.Y.

**CHARGE:** 501(c)—while held for sale, the strength of the article fell below that which it was represented to possess; and 502(a)—the label statement "Chorionic Gonadotropin 2500 I.U." was false and misleading.

**DISPOSITION:** 9-14-60. Default—destruction.

**DRUGS FOR VETERINARY USE**

**6323. Veterinary drugs.** (F.D.C. No. 44204. S. Nos. 49-689 P, 60-413/4 P.)

**QUANTITY:** 18 1-lb. cans, 5 10-lb. drums, 1 50-lb. drum, and 2 100-lb. drums, of *Vetrodine* and 16 ctns., each containing 50 boluses (12½ grams), and 24 ctns., each containing 50 boluses (8 grams), of *phenothiazine*, at Portland, Oreg.

**SHIPPED:** Between 6-26-59 and 12-16-59, from El Cerrito, Calif., by Vetrochem.

**LABEL IN PART:** (Can or drum) "Vetrodine An Iodine Compound for live-stock only \* \* \* Each pound contains: Ethylenediamine Dihydriodide 21

grams \* \* \* Directions for use \* \* \* Vetrochem \* \* \* Berkeley 10 \* \* \* El Cerrito, Calif," and (ctn.) "Phenothiazine Boluses With Lead Asenate \* \* \* Grams For elimination of Tapeworms, Stomach, Hook and Bankrupt Worms in Sheep and Goats. Each Bolus Contains: Phenothiazine 12.5 gms. [or "8 gms."] Lead Arsenate .5 gms. \* \* \* Manufactured by Vetrochem \* \* \* El Cerrito, Calif. 281."

ACCOMPANYING LABELING: Pamphlets entitled "Only a Healthy Herd Can Be Productive" and leaflets entitled "Vetrodine The Carrier's the Difference!"

LIBELED: 2-17-60, Dist. Oreg.

CHARGE: 501(c)—when shipped, the strength of the article of *phenothiazine boluses* differed from that which it purported or was represented to possess; 502(a)—the label statement "Phenothiazine 12.5 gms. [or "8 gms.]" was false and misleading as applied to an article which contained substantially less than 12.5 grams [or "8 grams"] of *phenothiazine* per bolus; and the labeling of the article of *Vetrodine* contained false and misleading representations that the article was an adequate and effective treatment for controlling lumpy jaw and diseases of cattle associated with *Actinomyces necrophorus* infections of soft tissue found in lung and liver abscesses; and the labeling statement "The name is synonymous with Foot Rot and other iodine therapy" which implied that the article was effective wherever iodine therapy was indicated in animals, was false and misleading since it was contrary to fact.

DISPOSITION: 7-18-60. Vetrochem, claimant, having consented to the entry of a decree without admitting the alleged adulteration or misbranding and the court having found that the articles were adulterated and misbranded as alleged, judgment of condemnation was entered and the *phenothiazine boluses* were ordered destroyed and the *Vetrodine* was ordered released under bond for relabeling.

## DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

### DRUGS FOR HUMAN USE\*

6324. Provimin Hair Rectifier. (F.D.C. No. 44582. S. No. 43-613 R.)

QUANTITY: 25 2-oz. btls. at Seattle, Wash.

SHIPPED: 9-8-59, from San Jose, Calif., by Tiffeny Products.

LABEL IN PART: (Btl.) "(59 cc.) 2 Ounces Proteins Vitamins Minerals Provimin Hair Rectifier For Sick Hair For Damaged Hair For Normal Hair Protection Tiffeny Products Distr. San Jose, Calif. Proteins Contained: \* \* \* Vitamins Contained: \* \* \* As prescribed by The Licensed Beautician. For \_\_\_\_\_ No. \_\_\_\_\_ Directions: \* \* \* By \_\_\_\_\_."

Licensed Beautician

ACCOMPANYING LABELING: Leaflets entitled "Provimin did it."

LIBELED: 5-18-60, W. Dist. Wash.

CHARGE: 502(a)—when shipped, the label designation "Hair Rectifier" and the other labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for correcting and preventing hair damage, and for producing healthy hair.

DISPOSITION: 8-1-60. Default—destruction.

\*See also Nos. 6302, 6304-6307, 6309, 6313-6315, 6317-6322.